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## Congress of the United States House of Representatives

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ON THE CLIMATE CRISIS

March 19, 2020

Stephen M. Hahn  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

Dear Commissioner Hahn:

I write regarding the U.S. Food and Drug Administration (FDA)'s release of guidance to clarify regulatory questions regarding pharmaceutical production of alcohol-based hand sanitizers for consumer use for the duration of the public health emergency due to the COVID-19 pandemic. In short, I respectfully request that you confirm that the aforementioned guidance also applies to FDA registered distilled spirits plants ("DSPs" or "distilleries") and provide guidance that gives DSPs the appropriate flexibility to either donate or sell the alcohol-based hand sanitizer they produce.

As you know, COVID-19 is rapidly spreading across the United States, with confirmed case numbers changing by the hour. Public health officials have made it clear that everyday preventative actions such as washing your hands can make an essential difference in helping to stop the spread of COVID-19. However, the rise in consumer demand for hand sanitizer has led to a shortage of this critical product, with several distilleries across the country filling the void by transitioning their traditional operations into a production line of alcohol-based hand sanitizer.

Over the last week, DSPs have made it clear that they are eager to help their communities during this public health emergency. It would be unconscionable for distilleries to follow the FDA pharmacy guidance to only find out down the road that they were not in compliance. Yesterday, the Alcohol and Tobacco Tax and Trade Bureau ("TTB") issued guidance that "any existing DSP [...] can immediately commence production of hand sanitizer or distilled spirits (ethanol) for use in hand sanitizer [...] without having to obtain authorization first." TTBs guidance authorizes distilleries to use hand sanitizer products consistent with World Health Organization ("WHO") advice, which is in accordance with the FDA's recent guidance to pharmacies regarding compounding alcohol-based hand sanitizer products during the public health emergency.

Due to the rapid spread of COVID-19 across the country and the scarcity of this critical product, we need to use all tools available to combat this public health threat. Our distilleries are in a unique position to help address the hand sanitizer shortage facing our communities, and it is my hope that you swiftly confirm that the FDA pharmacy guidance also applies to DSPs and allows for flexibility on whether distilleries can sell or donate the product.

I look forward to your prompt attention to this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Joe Neguse", is written over a faint, light blue rectangular background.

Joe Neguse  
Member of Congress